

K083145

9.

510(K) SUMMARY

9.0 510(K) SUMMARY

JAN 12 2009

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

APPLICANT Asahi Intecc Co., Ltd.
1703 Wakita-cho, Moriyama-ku
Nagoya, Aichi 463-0024
Japan

**OFFICIAL
CORRESPONDENT** Yoshi Terai
President, CEO
Asahi Intecc USA, Inc.
2500 Red Hill Avenue, Suite 210
Santa Ana, CA 92705
Tel: (949) 756-8252
FAX (949) 756-8165
e-mail: yoshi@asahi-intecc.com

TRADE NAME: Asahi Guide Wire Extension (accessory)

COMMON NAME: Guide Wire Extension

**CLASSIFICATION
NAME:** Wire, Guide, Catheter

**DEVICE
CLASSIFICATION:** Class 2 per 21 CFR §870.1330

PRODUCT CODE DQX

PREDICATE DEVICE: Asahi JoWire Neo's PTCA Guide Wire – K022762
Asahi Treasure 12 Peripheral Guide Wire – K061984

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Asahi Guide Wire Extension accessory is used to elongate the working length of compatible Asahi PTCA and Peripheral extendable wires. The stainless-steel Asahi Guide Wire Extension has an outer diameter of 0.014" (0.36mm) and a length of 150cm. Its distal end bears preformed elastic connecting tube. The product is specially designed to use with Asahi PTCA and Peripheral extendable guide wires. This product is a non-invasive medical device, and it is not contact with tissue and body fluids.

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INDICATION FOR USE:

The Asahi Guide Wire Extension accessory is intended for extension of the working length of an already introduced guide wire when exchanging over-the-wire interventional devices during an angioplasty procedure.

TECHNICAL CHARACTERISTICS:

The Asahi Guide Wire Extension accessory is made of the same materials that have been used in other predicate devices that are labeled for the similar indications. The dimensional specifications are equivalent to those listed for the currently cleared predicate devices.

PERFORMANCE DATA:

Enclosed within this submission is performance data that demonstrates that the Asahi Guide Wire Extension accessory meets all predetermined performance criteria.

SUMMARY/CONCLUSION:

The Asahi Guide Wire Extension accessory characteristics are substantially equivalent to the specified predicate devices and other currently marketed devices for the same indication for use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Asahi Intecc Co., Ltd.
c/o Asahi Intecc USA, Inc.
Mr. Yoshi Terai
President, CEO
2500 Red Hill Ave, Suite 210
Santa Ana, CA 92705

JAN 12 2009

Re: K083145
Trade/Device Name: Asahi Guide Wire Extension
Common Name: Guide Wire Catheter
Regulation Number: 21 CFR 870.1330
Regulatory Class: II
Product Code: DQX
Dated: December 12, 2008
Received: December 12, 2008

Dear Mr. Terai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

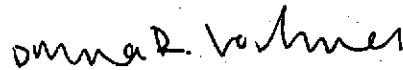
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set


forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0210. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



 Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2.

INDICATIONS FOR USE STATEMENT

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510(k) Number (if known): K083145

Device Name: Asahi Guide Wire Extension

Indications for Use:

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Prescription Use X

AND/OR

Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D)

(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diana D. Bohmer
(Division Sign-Off)
Division of Cardiovascular Devices

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